Global Regulatory Policy

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 04N-0242
Proposed Rule; Institutional Review Boards; Registration Requirements

Merck & Co., Inc., is a leading worldwide, human health product company. Merck's corporate strategy -- to discover new medicines through breakthrough research -- encourages us to spend more than $3 billion annually on worldwide Research and Development (R & D). Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the important pharmaceutical products on the market today.

In response to the Agency's July 6, 2004, *Federal Register* notice proposing to require Institutional Review Boards (IRBs) to register at a site maintained by the Department of Health and Human Services (HHS), we provide the following responses on three topics that are of interest to Merck as an IND sponsor:

Circumstances in which foreign IRBs should be required or invited to register?
The registration of foreign IRBs, also known as Ethical Review Committees (ERCs) or Institutional Ethics Committees (IECs) should remain voluntary, as is the current practice when ERCs register with the Office for Human Research Protections (OHRP) to obtain a federal wide assurance. ERCs may register with HHS in order to receive educational materials and share best practices. The vast majority of research reviewed by ERCs is independent of U.S. IND regulations; therefore, HHS should respect the oversight of ERCs by local authorities and not impose additional bureaucracy. We suggest that HHS solicit feedback on this topic directly from representative ERCs abroad.

How to best ensure that all sponsors and investigators involved in clinical investigations using human subjects use only registered IRBs to review and approve those clinical investigations?
HHS can facilitate the use of registered IRBs by investigators and sponsors conducting clinical research under an IND by creating a simple electronic system through which the majority of IRBs may register. HHS should permit IND sponsors and investigators ready access to the electronic system in order to confirm IRB registration. Written registration should remain an option to electronic registration for up to 24 months.

Are additional changes to FDA regulations necessary?
Additional regulations are not needed to ensure that IND sponsors use only registered IRBs to conduct clinical trials. Existing regulations are adequate to ensure that sponsors utilize registered IRBs. The existing regulations are clear regarding the obligation for IND sponsors and investigators to use IRBs that comply with 21 CFR 56. Currently, 21 CFR 312.66 requires that investigators use IRBs that comply with 21 CFR 56 (including proposed section 56.106). Before permitting an investigator to participate in an investigation, 21 CFR 312.53(vii) requires that sponsors obtain a commitment by the investigator that the investigation is subject to oversight by an institutional review board under Part 56. Failure to do so places sponsors in violation of their current regulatory obligations. Therefore, additional regulation is not necessary. FDA should not expend resources to revise the IND regulations, but rather promote awareness of these new regulations.

We appreciate the opportunity to comment on this proposed rule. If you have any questions, please contact me at 301-941-1403.

Sincerely,

Lauren M. Hetrick

Lauren M. Hetrick
Director, Global Regulatory Policy